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Congress of the United States
House of Representatives

COMMITTEE ON SCIENCE, SPACE, AND TECHNOLOGY

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October 12, 2017

The Honorable Scott Pruitt
Administrator
U.S. Environmental Protection Agency
1200 Pennsylvania Avenue, NW
Washington, D.C. 20460

Dear Administrator Pruitt:

The Committee on Science, Space, and Technology held a hearing on September 6, 2017, to examine the operational and scientific integrity of the Integrated Risk Information System (IRIS) program at the U.S. Environmental Protection Agency (EPA) Office of Research and Development (ORD). This hearing expanded upon issues raised in reports from the National Academy of Sciences (NAS)[1] and the U.S. Government Accountability Office (GAO).[2] In light of this information, the Committee is concerned about persistent issues regarding the difficulty to correct IRIS assessments that appear to use low-quality science to justify results. Moreover, it appears a troubling pattern has emerged with regard to the IRIS program in which credible scientific evidence is disregarded when amendments and corrections are requested for assessments. Lastly, the Committee is concerned about the merit of IRIS assessments completed prior to EPA adopting NAS-recommended reforms to its processes and science.

In 2010, EPA released a final toxicological review of chloroprene,[3] which reported an extremely high Inhalation Unit Risk (IUR) value. A detailed evaluation of the chloroprene assessment performed by a group of scientists later concluded that EPA's proposed IUR for

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[1] *See* Review of EPA's Integrated Risk Information System, Nat'l. Research Council of the Nat'l. Academies, https://www.nap.edu/catalog/18764/review-of-epas-integrated-risk-information-system-iris-process, (2014).
[2] *See* Transforming EPA's Process for Assessing and Controlling Toxic Chemicals, GAO 2017 High Risk List, https://www.gao.gov/highrisk/transforming_epa_and_toxic_chemicals/why_did_study#t=2, (Feb. 15, 2017).
[3] IRIS Toxicological Review of Chloroprene (Final Report), U.S. Environmental Protection Agency, EPA/635/R-09/010F, (2010).

chloroprene is 156 times greater than that which can be accurately derived by science.[4] The report offered to EPA also found that the IRIS assessment gave equal weight to studies used to make the IUR determination regardless of the study quality and that the agency ignored the conclusion of the highest quality study published on human exposure to chloroprene.[5]

As a result of the 2010 IRIS assessment, Denka Performance Elastomer, a chloroprene manufacturer, has spent more than $18 million on pollution control and been subject to reputational damage as a result of a National Environmental Investigations Center inspection and enforcement action.[6] Accordingly, Denka has requested that EPA withdraw and correct its 2010 IRIS review on chloroprene under the Information Quality Act (IQA) based on the scientific reports.[7] That request is still pending before the agency.

Similarly, the Halogenated Solvents Industry Alliance submitted a Request for Correction (RFC) under the IQA seeking to correct concentration and dose values in the IRIS assessment for trichloroethylene (TCE) in 2013.[8] This RFC also demonstrated that EPA chose to rely upon an inaccurate study as the primary basis for its conclusion.[9] A peer review meeting report for EPA's draft Toxic Substances Control Act Work Plan on TCE in 2013 questioned why EPA chose to rely upon this deficient study and suggested that the agency did not consider all relevant studies in its analysis.[10] However, despite these assertions, EPA ultimately denied the RFC in 2016.[11]

Failing to grant reviews of IRIS assessments that clearly rely upon low-quality data is an indication that EPA has ignored the best available science. As IRIS determinations are important markers for understanding the risk of chemicals in the natural environment, this practice is unacceptable for an agency that is entrusted to protect the health of the American people. We are all committed to establishing the highest level of scientific integrity, in which review and reassessment are integral parts. Unfortunately, it appears that the IRIS program does not live up to these scientific ideals.

The two above mentioned assessments on chloroprene and TCE are just some of the more well-documented cases of the failure of the IRIS program to take additional scientific information into account. These issues along with the numerous problems mentioned in the

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[4] *Examining the Operational and Scientific Integrity of EPA's IRIS Program: Hearing before the Subcomm. on Environment and Subcomm. on Oversight, 115th Cong. (2017) (Statement of Dr. Kenneth Mundt).*
[5] *Id.*
[6] Denka Performance Elastomer Letter to Administrator Pruitt Requesting EPA to Withdraw and Correct 2010 IRIS Review of Chloroprene, (June 26, 2017).
[7] RFC 17002, https://www.epa.gov/quality/rfc-17002, (June 26, 2017).
[8] RFC 14001, https://www.epa.gov/sites/production/files/2015-06/documents/14001.pdf, (Nov. 5, 2013).
[9] See *Id.*
[10] *Id* at 10.
[11] EPA response to RFC 14001, https://www.epa.gov/sites/production/files/2016-03/documents/14001a-response.pdf, (Feb. 26, 2016).

2011 NAS report raises legitimate concerns as to the quality of existing IRIS assessments. The 2011 NAS report effectively put EPA on notice of problems with the program and its processes.[12] Rather than begin the process of prioritizing and reviewing potentially deficient past assessments, EPA continued to push out assessments without adopting NAS recommendations. It is unfortunate that failure to review has become the norm for the IRIS process, raising serious questions about its viability as a trusted source for chemical risk assessment.

Nevertheless, on September 1, 2017, Dr. Peter Thorne, Chair of EPA's Chartered Science Advisory Board (SAB), sent you a letter regarding supposed improvements within the IRIS program.[13] The letter expressed SAB's opinion that recent changes to the program "constitute a virtual reinvention of IRIS."[14] However, the letter fails to take into consideration the fact that GAO placed the IRIS program on the High Risk List, a list of federal programs that are "especially vulnerable to waste, fraud, abuse and mismanagement, or that need transformative change," just six months prior to the letter for the eighth year in a row.[15] SAB also ignores the plethora of issues the report points out as still plaguing the IRIS program, including lack of transparency and mismanagement of resources.[16]

Furthermore, the SAB makes no mention of how EPA plans to address and correct past assessments performed while the program was deficient, including potentially faulty assessments like the ones completed for chloroprene and TCE. Given that the IRIS program appears to continually reject requests for correction based on credible scientific data, there appears to be no means of establishing the scientific integrity of the program as a whole.

To better assist the Committee in understanding how EPA intends to uphold scientific integrity and how it undertakes decisions to grant scientific and informational quality requests with regard to IRIS assessments, we request a staff briefing by appropriate EPA staff on this matter. We ask that you schedule this staff briefing no later than Thursday, October 19, 2017. Further, we request all documents and communications referring or relating to RFCs of IRIS assessments submitted, considered, rejected, or accepted since January 20, 2009.

We request that you provide these documents and information as soon as possible, but no later than 5:00 p.m. on Thursday, October 26, 2017. When producing documents to the Committee, please deliver production sets to the Majority Staff in Room 2321 of the Rayburn House Office Building and the Minority Staff in Room 394 of the Ford House Office Building. The Committee prefers, if possible, to receive all documents in electronic format.

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[12] *See* Review, *supra* note 1.
[13] SAB comments on EPA's response to recommendations on the Integrated Risk Information System, https://yosemite.epa.gov/sab/sabproduct.nsf/LookupWebReportsLastMonthBOARD/A9A9ACCE42B6AA0E8525818E004CC597/$File/EPA-SAB-17-008.pdf, (Sept. 1, 2017).
[14] *Id.*
[15] U.S. Gen. Accounting Office, GAO-17-317, *High-Risk Series: Progress on Many High-Risk Areas, While Substantial Efforts Needed on Others* 1 (2017).
[16] *Id* at 419.

The Committee on Science, Space, and Technology has jurisdiction over environmental and scientific programs and "shall review and study on a continuing basis laws, programs, and Government activities" as set forth in House Rule X.

If you have any questions about this request, please contact Committee staff at 202-225-6371. Thank you for your attention to this matter.

Sincerely,

Rep. Lamar Smith
Chairman
Committee on Science,
Space, and Technology

Rep. Andy Biggs
Chairman
Subcommittee on
Environment

cc: The Honorable Eddie Bernice Johnson, Ranking Member, Committee on Science, Space, and Technology

The Honorable Suzanne Bonamici, Ranking Member, Subcommittee on Environment